UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

LUCY DELGADO,

Index No: 17-CV-03245

Plaintiff,

-against-

UNIVERSAL BEAUTY PRODUCTS, INC.

Defendant.

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DEFENDANT'S MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules

Other Sources

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Pursuant to Rule 56 of the Federal Rules of Civil Procedure, Defendant UNIVERSAL BEAUTY PRODUCTS, INC. respectfully submits the following Memorandum in support of the motion for summary judgment.

STATEMENT OF FACTS/INTRODUCTION

This is a products liability action brought by Plaintiff, LUCY DELGADO ("Plaintiff"), who seeks damages against Defendant, UNIVERSAL BEAUTY PRODUCTS, INC. ("Defendant"), stemming from her alleged use of a product known as Robert's Diamond Shield ("Diamond Shield" or "Product"). Plaintiff alleges that after using the product she suffered hair loss within two (2) weeks of its application to her scalp and hair. Plaintiff alleges that the product is inherently defective in both design and manufacture and unsafe, inadequate and unfit for the purposes for which designed and sold. They also claim the insured knowingly failed to put adequate warnings on the product.

The Defendant serves as a health and personal care company which sells products all over the United States (Exhibit C, at 23), as well as internationally, with over 200 products on the market (Id. at 45). The Roberts Diamond Bond ("the product") is a product that is used to form a shield around someone's head over their hair. It dries to make a very hard shell and the customer can apply glue on the shield and then attach hair to the glue. When applied properly, the product keeps the glue from touching the real hair (Exhibit C, at 96).

Prior to this alleged incident and report made to the Defendant by the Plaintiff, the Defendant has never received any complaints regarding this hair product by a customer, or otherwise. (Exhibit D, at 16-18). Plaintiff, who has brought this claim, has not to date, pointed out any other person who has used this product and has suffered hair loss. Plaintiff's expert, Dr. Spaeth

also could not cite to any other claims of hair loss involving this product and also admitted that it has never been subject to any recall and is still widely available on the market. (Exhibit "Q", at 75 and 128).

PLAINTIFF'S USE OF THE PRODUCT

Plaintiff testified that while she has never used the product prior to November 2015, she was actually introduced to the product by a friend who advised Plaintiff that the Diamond Bond product would protect the hair and allow for the attachment of hair extensions without any adhesive or glue touching the hair. (Id. at 25 and 28). The friend also told her to try it, as the product is great. (Id. at 28).

After applying the product with a glue made by another Company in contradiction with the instructions, Plaintiff felt itching within a day. The Diamond shield on her head made it impossible for Plaintiff to scratch her scalp so she would simply tap her head to stop the itching. (Id. at 57). After one day, the itching just got progressively worse. (Id. at 57). Plaintiff kept the Diamond Bond on for approximately two weeks despite the continued and progressive itching on her scalp. (Id. at 58 and 60). She testified, when she finally washed the product out of her hair, portions of her hair fell out. (Id. at 60). Plaintiff did not know of anyone who had the same experience with the Diamond Bond product. (Id. at 92).

Plaintiff eventually spoke with Jocelyn Stephens about her experience with the product and Ms. Stephens took notes to memorialize her conversations with Plaintiff immediately after the phone discussions. (Ex. C. at 110-111). Joycelyn Stephens testified that she never received the product that Plaintiff claims she used on her hair from the Plaintiff. (Id. at 50-51). Ms. Stephens' notes from her conversation with Plaintiff on December 16, 2015, indicate that Plaintiff had sent her pictures and a bag of hair but did not send the product. (**Exhibit "J"**). Ms. Stephens

recommended conditioner, but Plaintiff refused and said she wanted her hair and photos sent back to her. (Id.)

Ms. Stephens sent the materials to her insurance broker, Biglow and Biglow, and returned Plaintiff's hair samples and photos to her attorney on June 29, 2016. (**Exhibit "K"**). Plaintiff's counsel sent a reply letter on July 12, 2016 confirming receipt of the hair samples and photos. The letter asks about additional hair but there is no mention regarding the actual product. (**Exhibit "L"**).

ALL OF THE SCIENTIFIC EVIDENCE ESTABLISHES THAT THE PRODUCT IS SAFE AS DESIGNED

Defendants produced Barry Williams for a Deposition. Mr. Williams is employed by Universal as a Chemist (Exhibit E, at 4-5) and has a degree in Biochemistry, (Id. at 11). Batch sheets for the Product were produced by the Defendant and were identified by Mr. Williams at his deposition. The batch sheets contained the ingredients and instructions on how to make the product. (Id. 14 and Exhibit F). Mr. Williams testified that he reviewed all the data sheets and testing materials for the Robert's Diamond Product prior to the deposition, (Id. at 12), including each ingredient in the product and confirmed that none of the ingredients cause hair loss (Id. at 26). Barry Williams then reviewed the safety data sheet for the product, (Id. at 14 and Exhibit G). The safety data sheet confirms it is safe to be used on skin and is classified as non-irritant. (Exhibit G, at 3). While Plaintiff seems to claim that Polyvinyl alcohol is not safe for use over 3%, the safety data sheet lists Polyvinyl alcohol at 10 to 20% and it is classified as a non-irritant. (Id.).

Defendants retained Dr. Anne Harman Chappelle, Ph. D, DABT to review the product and discovery in this case. (Report and CV annexed as Exhibit "P"). Dr. Chappelle confirmed that all

the ingredients used in the Roberts Diamond Bond product were tested with direct skin contact under occlusive conditions and were determined to be safe without risk for hair loss. (Id at 3-8).

Plaintiff, in his Rule 56.1 response and during oral argument seemed to rest a large portion of his case on the allegation that Polyvinyl alcohol is only approved up to 3% and the Diamond Bond Product used over 10% and therefore was over three times over safe limit and cites to a CIR study in Dr. Chappelle's report. (Plaintiff's rule 56.1 at 68). However, this claim is clearly mistaken and directly contradicted by both experts in this case.

On Page 3 of her report, Dr. Chappelle provides that Recipe A for the product used 11.4% Polyvinyl Alcohol. (Exhibit "P", at 3). On the same line of the chart, she provides the human testing that was done and shows that it was tested under an occlusive patch directly to the human back at 13% for 21 consecutive days with a total irritation score of 10 out of 756. (Id). It was also tested at 13% with a peel off face mask with "barely perceptible irritation" and "no reactions observed during challenge". (Id.) Under Comments on the same line, Dr. Chappelle reports the "CIR concludes that PVA (polyvinyl alcohol) does not raise concern at "**up to 15%".** (Id.)

To further put this issue to rest, Plaintiff's own expert Dr. Spaeth issued a report dated August 31, 2020. (Report annexed as **Exhibit "S"**). On page 4 of his report, Dr. Spaeth states that "In Roberts Diamond Bond Protective Shield Hair and Scalp Protection Kharkoal, based on the batch sheets provided, poly-vinyl alcohol is the primary polymer; however, poly-ethylene glycol is also used to form an occlusive barrier. On their own, these chemicals are inert and fall under the polymers of low concern." (Id. at 4). Dr. Spaeth never makes the claim in any report or in his testimony that the product contained elevated levels of Poly-vinyl alcohol and in fact admits it is a chemical of low concern.

Since Plaintiff has no scientific data to back up his claims, he repeatedly misstates the record as shown above and again in his Rule 56.1 response at 103. Plaintiff disputes the components of Diamond Bond were tested under an occlusive barrier with direct skin contact, but this is clearly false. As shown above, Polyvinyl Alcohol was tested up to 15% under an occlusive barrier with direct skin contact and was found to be safe. Based on the undisputed facts, there can be no argument that Defendant used an excessive or unsafe amount of Polyvinyl Alcohol so now that this issue is put to rest, we will move onto Dowicil 200, which makes up the rest of Plaintiff's claim of a product defect.

Dowicil 200 was tested under an occlusive patch for 21 days for 23 hours a day directly to the human back at .3%. This test showed a total irritation score of .83 out of 630 and was classified as "non-irritating". (Exhibit "P", at 3). Plaintiff's allegation in this case is not that she had some mild irritation. She is claiming she sustained permanent hair loss and cell death. Once again, the experts are in agreement as Dr. Spaeth testified that "They tested .3 percent quaternium-15 (Dowicil 200) on an occlusive patch for 23 hours a day, 21 consecutive days. At this level it was found to be non-irritating". (Exhibit "Q", at 142-143). Dr. Spaeth confirmed that "**up to .3% was non to mildly irritating**. Higher could cause sensitization based on the data". (Id. at 143). This is Plaintiff's expert, not Defendants.

Giving Plaintiff the benefit of the doubt that she used the batch recipe with the highest level of Dowicil 200 of Quartenium-15, the level would be .375, which is slightly above the .3 percent that was tested under an occlusive patch with direct skin contact for 21 days and determined to be "non to mildly irritating". However, when asked, Dr. Spaeth testified that "I'm not sure that the .375, the additional .075 percent, would cause massive changes relative to .3 percent." (Id. at 144). In regard to the direct issues in the case, Dr. Spaeth admitted he has never seen any testing or any

data on Dowicil 200, quartenium-15 to support that is causes actual cell death and permanent hair loss. (Id. at 145).

Again, the testing done under much more severe conditions than those used by the Diamond Bond Product, since that would be applied to the hair and not direct skin does not even show irritation at .3 percent. Here, Plaintiff is trying to claim that at .375 it causes permanent cell death and hair loss. There is simply no scientific data to remotely support this and the scientific date specifically refutes this claim.

All experts agree the ingredients in the Diamond Bond protective shield are widely and safely used in cosmetic and consumer product formulations. (Exhibit "P". at 13 and Exhibit "Q", at 50-51). All companies that sell cosmetics are using the same preservatives. (Exhibit "Q", at 55). Based on the scientific testing, the product is not considered toxic, corrosive, an irritant, or strong sensitizer. The Federal Hazardous Substance Act would not require the bottle to contain a warning. (Exhibit "P"). All of the testing to support this claim is cited by Dr. Chappelle and not disputed by Dr. Spaeth. (Id.)

Dr. Spaeth never reviewed the Safety Data sheets for the subject product. (Exhibit "Q". at 31). This Safety Data Sheet was provided in discovery and annexed as Exhibit "G". Dr. Spaeth did not know what other products Plaintiff applied to her hair on the same day she used the Diamond Bond product. (Exhibit "Q". at 35). Dr. Spaeth was not aware of any products in the cosmetics industry that contained warnings about permanent hair loss. (Id. at 54). The preservatives used in the Diamond Bond product underwent extensive studies and are acceptable for use in cosmetics. (Id. at 57). All the preservatives used in the Diamond Bond product were tested under an occlusive barrier with direct skin contact. (Id. at 60).

Just to eliminate any confusion, Dr. Spaeth testified that in regard to use with direct skin contact, "All of the individual ingredients have been approved for use, and in one of the batches there is a slight concentration that is slightly higher than what has been approved, but in general for nearly every ingredient, they are within acceptable use percentage defined by either the CIR or by the European Union." (Id. at 62). As discussed above, the "slightly higher" concentration referred to by Dr. Spaeth was the .375 Dowicil, which he testified would not cause any "massive changes".

Plaintiff's expert had to admit that there are no studies that indicate any chemicals used in the Diamond Bond product can cause permanent hair loss. (Id. at 69). There are only studies that indicate that preservatives can cause irritation if left on more than 7 days. (Id. at 69). All preservatives used by Universal were extensively tested by the relevant agencies and "strongly validated for use in Europe as well as the United States." Id. at 117-118. The preservatives used by Universal are acceptable at the concentrations used in the Diamond Bond Product. (Id. at 122). The concentrations used by Universal in the Diamond Bond product were tested under an occlusive barrier with direct skin contact and they were found not to damage hair or skin cells. (Id. at 124-125). While Plaintiff tries to dispute some of these claims, the testimony is clear and the Court can simply refer directly to the testimony of Plaintiff's expert, Dr. Spaeth.

Based on the testing data and testimony of both experts, Defendants designed and marketed a product containing ingredients that had all been cleared for use at the concentrations used and all underwent vigorous testing with direct skin contact under an occlusive barrier for up to 21 days and determined to be safe. There is simply not even an allegation that is backed up by any science that the product was defectively designed or not safe for its intended use. Dr. Spaeth specifically admitted that in order to cause hair loss, there would need to be higher concentrations of

preservatives than shown on the batch sheets for this product. (Id. at 206). While Plaintiff tries to speculate that somehow his client got a magic bottle containing different ingredients than any other bottle sold in the world, there is no evidence to back this up. The facts establish that the Diamond Bond product does not cause permanent hair loss. Any claim to the contrary is pure speculation and can't be considered by this Court. While it is true that the formula has changed since 2015 it still uses the same components to form an occlusive barrier and uses the same preservatives. This product is safe and is still widely available.

PLAINTIFF STILL HAS NO IDEA WHAT CAUSED HER ALLEGED HAIR LOSS

Since Plaintiff never got any patch testing or made any attempts to find out what caused the irritation to her scalp, there is simply no scientific evidence to show what came in contact with Plaintiff's scalp and what caused her hair to fall out. It could be an allergic reaction, could be glue, could be dampness on her scalp from not drying sufficiently or an endless number or reasons. It is not Defendants burden to prove what caused Plaintiff's alleged injury, it is Plaintiff's burden to prove that some actionable defect in the product caused her condition and Plaintiff simply has none. Dr. Spaeth never examined Plaintiff and never even reviewed her deposition or photos. He has no idea what her alleged injury even is and he certainly has no idea what caused the alleged permanent hair loss. All he could say is that this product could lead to some irritation if left on for more than 7 days. That is the strongest claim he could make based on the science and the data. Again, this case is not about alleged irritation after seven days, it is a claim of permanent hair loss.

Furthermore, there is no dispute that Plaintiff did not follow the directions on the bottle and used a glue made by an outside company. The Plaintiff used Lanell's hair bonding glue and that glue contains a warning stating "This product contains natural rubber latex which may cause

allergic reactions in some individuals. Do not put on scalp. Do not use if scalp is injured or irritated. Keep out of eyes. To avoid hair loss, do not pull. To remove, use Lanell Hair Bond remover. Keep out of reach of children." (Exhibit "H" at 46-47 and Exhibit "R"). While Plaintiff argues there is no evidence that the glue came in contact with Plaintiff's scalp, there is also no evidence that any portion of the Diamond Bond product went through Plaintiff's hair and came in contact with her scalp. This evidence is not available to any party since Plaintiff simply did not seem interested enough to try to find out what had caused her head to itch for two weeks. While Plaintiff alleges this was some life altering event, she saw a dermatologist one time, ignored his instructions and never underwent any testing or treatment to her scalp.

Unlike the Diamond Bond product, Dr. Spaeth testified that hair glues do cause fungal infections and many forms of irritation on the scalp. (Exhibit "Q", at 101). Glues contain latex, which are a sensitizer. (Id. at 101). Glues can cause irritation and sensitization of the skin. (id. at 102). Glues can also cause hair loss. (Id. at 102-103). Fungal infections can cause cell death and permanent hair loss. (Id. at 103). Ms. Delgado was aware the glue causes hair loss and still left it on her hair for two weeks despite the warning on the glue and severe itching within 24 hours. (Id. at 109). Unlike the Diamond Bond product, there is actual evidence that the glue causes hair loss. While it is true, the Diamond Bond is designed to keep the glue off the scalp, there is no way to prove whether Plaintiff applied the product properly or covered her entire scalp. There was no one who witnessed Plaintiff apply the product and we already know she failed to follow the directions. Plaintiff had never used the Diamond Bond before the time of this incident so she had no reason to believe that severe itching was somehow a normal response that should be ignored even if you have glue on your head.

FAILURE TO WARN CLAIM

There is no dispute that Plaintiff had a product on her head that included a warning about potential for injury including hair loss. Plaintiff ignored that warning and left the glue on her head for two weeks despite severe itching. Plaintiff also had her own warning of severe itching, which she also ignored for two weeks. Since Plaintiff can't make out a claim for a design or manufacturing defect, she is left with the failure to warn claim. Defendants admit the subject Diamond Shield product did not contain a warning. Dr. Chappelle stated that since the product is not an irritant or a sensitizer, no warning is required. (Exhibit "P"). Dr. Spaeth agrees with Dr. Chappelle's conclusion on page 10 of her report that the Diamond Bond product as described in the batch sheets is not likely an irritant and not likely a sensitizer. (Ex. P at 10, and Ex. "Q". at 169).

Dr. Spaeth opined that the Diamond Bond product should have contained a warning that it should not be left on for more than 7 days or irritation could occur. (Id. at 114). According to Dr. Spaeth, that warning would be sufficient. (Id. at 115). Plaintiff felt irritation within 24 hours and yet did nothing so it is hard to see how a warning regarding potential irritation after 7 days would have made any difference to her.

Dr. Spaeth testified that a warning stating "Flammable. For external use only. Keep out of reach of children. Do not pull tracks or wefts. Keep away from eyes. If contact occurs, rinse thoroughly with warm water", would also have been sufficient. (Id. at 133-135). Dr. Spaeth agreed that "A warning that use of the product may result in temporary or permanent hair loss would not have been appropriate and is not supported by the Data", in regard to the Diamond Bond product. (Id. at 183). Dr. Spaeth does not specifically disagree that a warning is not required but states "I think that an argument could be made that it was required". (Id at 182). That's the best

Plaintiff's expert could provide is that "an argument could be made". This is not legally sufficient to make out a failure to warn claim.

As will be discussed below, in order to make out a failure to warn claim, Plaintiff needs to establish the product required a warning and the lack of warning was a proximate cause of the injury. Even granting that "an argument could be made" the product required a warning stating it should not be used for more than 7 days or irritation could occur, there is no basis to argue the failure to place this warning was the proximate cause of the injury. Plaintiff already had a toxic glue on her head that contained a more severe warning and she ignored severe itching for two weeks. It's hard to see how alerting her that she might feel some irritation after seven (7) days without washing her hair would have made any difference. Plaintiff can't claim that his client really did not understand that putting on hair products like glue and feeling severe itching was not a sufficient warning that her body was trying to tell her something.

Defendant is entitled to a summary judgment in all claims alleged by the Plaintiff against the Defendant as she has not established a genuine issue of material fact that this Product is faulty or otherwise defective so as to cause her hair to fall out.

STANDARD FOR SUMMARY JUDGMENT

Rule 56(a), F.R.C.P., states that "the court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."

Summary judgment should be entered against a party who, after adequate time for discovery and upon motion, fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). By its very terms, this standard provides that the mere existence of some alleged factual dispute between the parties will not defeat an otherwise

properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact. *Anderson v. Liberty Lobby*, 477 U.S. 242 (1986).

As to materiality, the substantive law will identify which facts are material. Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted. 10A C. Wright, A. Miller, & M. Kane, Federal Practice and Procedure § 2725, pp. 93–95 (1983). Furthermore, summary judgment will not be granted if the material fact is not "genuine", that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.

Rule 56(e) provides that, when a properly supported motion for summary judgment is made, the adverse party "must set forth specific facts showing that there is a genuine issue for trial." Rule 56(c) provides that the trial judge shall then grant summary judgment, if there is no genuine issue as to any material fact and if the moving party is entitled to judgment as a matter of law. There is no requirement that the trial judge make findings of fact. The inquiry performed is the threshold inquiry of determining whether there is the need for a trial—whether, in other words, there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party.

ARGUMENT

PLAINTIFF HAS PRESENTED NO GENUINE ISSUE OF MATERIAL FACT TO SUPPORT HER CLAIM THAT THE PRODUCT WAS INHERENTLY DEFECTIVE IN DESIGN AND/OR MANUFACTURE.

In recognizing a cause of action for strict products liability, "the manufacturer of a defective product is liable to any person injured or damaged if the defect was a substantial factor in bringing about his injury or damages; provided: (1) that at the time of the occurrence the product

is being used for the purpose and in the manner normally intended, (2) that if the person injured or damaged is himself the user of the product he would not by the exercise of reasonable care have both discovered the defect and perceived its danger, and (3) that by the exercise of reasonable care the person injured or damaged would not otherwise have averted his injury or damages." *Codling v. Paglia,* 32 N.Y.2d 330, 342, 345 N.Y.S.2d 461, 298 N.E.2d 622.

It is well established that "a defectively designed product is one which, at the time it leaves the seller's hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use" *Voss v. Black & Decker Mfg. Co*, 59 N.Y.2d 102, (1983). In order to recover on the basis that a product was designed defectively, "it must be established that the marketed product in question was designed in such a way that it is not reasonably safe and that the alleged design defect was a substantial factor in causing the Plaintiff's injuries" *Gonzalez v. Delta Intl. Mach.,* 307 A.D.2d 1020 (2nd Dept. 2003).

"A design defect claim . . . is premised on a manufacturer's failure to properly design a product, which is then placed on the market despite posing inappropriate risks." *Reed v. Pfizer*, Inc., 839 F. Supp. 2d 571, 577 (E.D.N.Y. 2012). In order "[t]o state a claim for strict products liability under a design defect theory, a plaintiff must allege that '(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury." *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 403 (S.D.N.Y. 2013) (quoting *Colon v. BIC USA,* Inc., 199 F. Supp. 2d 53, 83 (S.D.N.Y. 2001)); *Sullivan v. Aventis, Inc.*, 14-CV-2939, 2015 WL 4879112, at *7 (S.D.N.Y. Aug. 13, 2015*); Cavanagh v. Ford Motor Co.,* 13-CV-4584, 2014 WL 2048571, at *2 (E.D.N.Y. May 19, 2014).

As shown above, each and every ingredient in the Diamond Bond product was tested and approved for use and the concentrations used. There is zero evidence anywhere that anything in this product was not safe for its intended use. There is no evidence of any person ever sustaining permanent hair loss as a result of the use of the product and it has never been subject to any recalls. While the formula has changed since Plaintiff used it in 2015, it still contains the same polyvinyl alcohol and preservatives and is widely available up to the current date without incident or complaint. Defendants do not need to prove that it is impossible for any single person to have an adverse reaction to the product, they only need to prove the product is "reasonably safe" and since every ingredient was subject to and passed excessive testing under occlusive barriers it difficult to see what Defendants did wrong or should have done differently.

Plaintiff has failed to provide any evidence at all that any ingredient in the product manufactured by Defendant caused her hair loss. She used many more products including bond remover, shampoo, conditioner and another glue, not associated with the Defendant's product that may have caused her hair loss. Plaintiff has no evidence that it was the Defendant's product. Additionally, if Plaintiff felt discomfort at any time after use of the product, she should have removed it. The fact that she kept it in for an additional two (2) weeks after her apparent discomfort was her own negligence regardless of what was causing the discomfort.

Plaintiff's first visit to any medical professional concerning issues with hair loss, was when she visited the Delmont Medical Care, approximately 9 months after she washed the product out of her hair and noticed hair loss. (Exhibit H at 113 and Exhibit M). Plaintiff's medical history is significant for depression, anxiety, glaucoma and Alopecia (a condition referring to unexplained hair loss). (Id.).

Plaintiff then went to see Dr. Wininger on August 8, 2016 claiming she sustained hair loss after using a product. Upon examination, Plaintiff did have multiple circular areas of hair loss. There was no scarring. Plaintiff stated she had used a protective shield on her scalp in December, which she believes caused the hair loss. Dr. Wininger recommended Ketoconazole Shampoo, which is used to treat fungal conditions on the scalp and allergic reactions. (Id at 133 and Exhibit M.). As such, it is clear, the only medical professional who examined Plaintiff within a year of the incident believed she had either a fungus or an allergic reaction, neither of which would have anything to do with the Diamond Bond product. Even after being informed by a Doctor that an anti fungal shampoo could help her, Plaintiff admitted that she did not get the shampoo (Id. at 134) and did not follow the doctor's instructions and never went back to the dermatologist, or any other dermatologist. (Id. at 134-135).

Therefore, none of the medical records pertaining to Plaintiff and her hair loss has identified a single ingredient in the product, or the product itself which has caused or contributed to the Plaintiff's scalp to become irritated and to lose hair. Plaintiff's expert also agreed that none of the ingredients in the Diamond Bond cause the permanent hair loss that Plaintiff alleges.

As to the instructions which were noted on the bottle of the product for applying the product to the hair, Plaintiff admitted that she did not understand the first instruction on the bottle which stated that the consumer was to use "before and after conditioning shampoo" as shown in Step I on the bottle (Id. at 54 and Exhibit I) and agreed that she did not use the "protective shield adhesive bonder" as described in step 3 of the instructions on the bottle. (Id. at 55 and Exhibit I). Plaintiff also admitted that she did not research the instructions for clarity but that she used "any glue" because this was what she was told by a person who used it on her hair before. Plaintiff therefore did not use the product in the means prescribed on the product label.

The determination of a design defect requires a risk/utility analysis that involves consideration of whether, if the alleged defect was known at the time of manufacture, "a reasonable person would conclude that the utility of the product did not outweigh the risk inherent in marketing a product designed in that manner" *Denny v. Ford Motor Co.* 87 N.Y.2d 248. In a similar case, the Supreme Court Appellate Division of the Second Department found, "in order to prevail under theory of strict liability for injury due to a defective product, the injured party must prove, to reasonable exclusion of all other possible causes, through competent professional testimony, which could include but was not limited to testimony of dermatologist, beautician, licensed cosmetologist, chemist and her own personal physician, that the proximate cause of her hair loss was application of the product. The cornerstone rule in products liability is that proof of mere injury furnishes no rational basis for inferring that the product was defective for its intended use. *Helen Curtis Insus. v. Pruitt*, 5t Cir, 385 F.2d 841. The Plaintiff must demonstrate, at a minimum, that her injures are the direct result of the product applied to her hair and that those products are the sole possible cause of the injury. *Chaill v. Inecto* in. 208 App Div 191. Since Plaintiff was already losing her hair, and diagnosed with alopecia, it is impossible for her to relate her hair loss with the product.

Since Plaintiff is alleging the existence of design defects, she must provide expert testimony as to the feasibility and efficacy of alternative designs. See, e.g., *Maxwell v. Howmedica Osteonics Corp.*, 713 F.Supp.2d 84, 91 (N.D.N.Y. 2010); *Guarascio v. Drake Assocs., Inc.*, 582 F.Supp.2d 459, 463 (S.D.N.Y. 2008) ("New York courts uniformly rule that competent, non-conclusory expert testimony is needed in cases involving more complex design issues."); *Rypkema v. Time Mfg. Co.*, 263 F.Supp.2d 687, 692 (S.D.N.Y. 2003). "If plaintiff does not provide expert testimony regarding the alleged design defect, he must establish that "a reasonable alternative

design is both obvious to, and understandable by, a layperson." *Guarascio,* 582 F.Supp.2d at 463. Although plaintiff contends that "[i]t does not take an expert to explain, understand or solve" what he terms a "relatively simple design flaw," Pl. Obj. at 4, the Court does not agree that the alleged design flaws are "simple," or that they would be obvious to and understandable by a layperson. Thus, expert testimony is required." See, e.g., *Guarascio,* 582 F.Supp.2d at 464; *Tiner v. Gen. Motors Corp.*, 909 F. Supp. 112, 117 (N.D.N.Y. 1995); *Soliman v. Daimler AG*, 10-CV-408 (SJF) (AKT), at *5-7 (E.D.N.Y. Sep. 30, 2011). Dr. Spaeth admits all of the ingredients in the product are safe and were approved and he does not suggest any alternative design to create an occlusive barrier to shield hair from hair glue. His only issue is his claim the product should have contained a warning stating that if left on for more than 7 days, it could cause irritation.

Plaintiff has consequently placed no material issue of genuine fact before this Court to raise the slightest question that Defendant marketed a Product, which was not reasonably safe in its design. Plaintiff has failed to show the product is dangerous, and not reasonably safe in any way to have caused any damages to the Plaintiff. Even if she was able to prove harm, which is empathically denied, Plaintiff has also failed to show how or whether it was feasible to design the product in a safer manner. Again, both experts agree the product only used ingredients that all commonly used in the industry at concentrations that were tested and approved as safe.

PLAINTIFF HAS PRESENTED NO GENUINE ISSUE OF MATERIAL FACT TO SUPPORT HER CLAIM THAT DEFENDANT HAD A DUTY TO WARN HER OF DANGERS OF HAIR LOSS

It follows from the argument presented above, that since Plaintiff has failed to identify any ingredient in the product which is unsafe, or to show any inherent defect in its design or manufacture, Plaintiff has failed to show that Defendant owed her, or any other user of the product, the duty to warn of possible hair loss. Plaintiff has therefore failed to establish any genuine issue

of material fact to support her claim that the Defendant failed to warn Plaintiff of any possible defects in the product or any danger in using the product, which may cause hair loss.

Dr. Spaeth agreed that there is no data to support the requirement that the product contain a warning regarding the potential for hair loss. Dr. Chappelle stated the product did not require a warning at all since it was classified as a non-irritant and this is supported by all of the testing and data included in her report that is not disputed. There is simply no evidence to support the claim that Defendants were required to put a warning on the bottle regarding the potential for permanent hair loss, which is the only injury alleged in this case. There is also no evidence that even if Defendants put the mild warnings about potential for irritation after 7 days requested by Dr. Spaeth, that this would have had impact on Plaintiff who ignored a far more severe warning on the glue and the warnings of her own body. Clearly, she knew she was experiencing irritation long before 7 days and still did not wash her hair.

A failure to warn claimant must show (1) that a manufacturer has a duty to warn; (2) against dangers resulting from foreseeable uses about which it knew or should have known; and (3) that failure to do so was the proximate cause of harm. Failure to warn claims are identical under strict liability and negligence theories of recovery.

In New York, there is a presumption that a user would have heeded warnings if they had been provided, However, this presumption may be rebutted by specific facts showing that the warning would have been futile. Colon ex rel. Molina v. BIC USA, Inc., 199 F. Supp. 2d 53 (S.D.N.Y. 2001).

As outlined above, a court must deny a failure to warn claim as a matter of law where only one conclusion can be drawn from the established facts. In this case, the proposed warning about potential for irritation after 7 days would have been irrelevant since Plaintiff felt irritation

within 24 hours and left it on for two weeks anyway. She also had a product on her head that actually warned of hair loss and she completely ignored that warning. Plaintiff wants to argue that Plaintiff was so reassured that the Diamond Shield, which she had never used before was working so well that she did not have to worry about the glue so she could ignore that warning and the itching. This is simply ridiculous.

Where a danger is readily apparent as a matter of common sense, "there should be no liability for failing to warn someone of a risk or hazard which he [or she] appreciated to the same extent as a warning would have provided." (emphasis added); Hutton ("[I]f the plaintiff's testimony shows that he or she was aware of the danger to the extent that a warning cannot increase his awareness of its presence, and the warning would not have prevented the harm, a failure to warn cannot be the proximate cause."). Liriano v. Hobart Corp., 92 N.Y.2d 232, 700 N.E.2d 303 (1998).

Again, in this case, the only warning argued for is a warning about the potential for irritation after extended use of over 7 days. No one can argue Plaintiff was not aware of irritation long before 7 days. There is no data to support the argument that Plaintiff should have been warned that leaving the Diamond Shield on for too long would cause permanent hair loss.

Accordingly, plaintiffs' failure to warn claims must be dismissed as a matter of law.

PLAINTIFF FAILED TO SHOW ANY GENUINE ISSUE OF FACT THAT IT BREACHED ANY IMPLIED WARRANTY

Plaintiff alleges in her Complaint that Defendant warranted to all intended users including Plaintiff, that the product was of merchantable quality and fit for the purpose for which it was intended, designed, manufactured, assembled, inspected and sold. That, as a result of its improper manufacture, it has breached its warranties of merchantability and fitness for use. (Exhibit A).

A breach of implied warranty of merchantability is where a manufacturer's products are not fit for the ordinary purposes for which such goods are used. UCC 2-314(2)(c). "The focus of a breach of implied warranty inquiry is whether the product meets the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manners." *Denny v. Ford Motor Co.,* 87 N.Y.2d 248, 258-259, 639 N.Y.S.2d 250, 256 (1996).

To show breach of implied warranty, Plaintiff must show the following: "(1) that the product was defectively designed or manufactured; (2) that the defect existed when the manufacturer delivered it to the purchaser or user; and (3) that the defect is the proximate cause of the accident." *Simon,* 990 F. Supp. 2d at 407 (internal quotation marks and citation omitted); *Cavanagh*, 2014 WL 2048571, at *5. "Liability under strict products liability and implied warranty theory are essentially the same." Id. at *5 (internal quotation marks and citation omitted); Goldin, 2013 WL 1759575, at *5.

Again, all the experts agree the ingredients used were tested and safe for the intended use.

PLAINTIFF HAS FAILED TO SHOW ANY GENUINE ISSUE OF FACT TO SHOW THAT IT WAS CARELESS AND/OR NEGLIGENT IN THE MANUFACTURE OF PRODUCT

As previously outlined, Plaintiff has again failed to show by any expert or documentary proof or otherwise, that Defendant was negligent or careless in the manufacture of the product.

Under the theory of negligence, the Plaintiff is required to prove that the manufacturer failed to exercise reasonable care in making the product for its intended (normal) or foreseeable use, and that it failed to exercise reasonable care in inspecting or testing the product. It is New York law that Defendants cannot be held to a higher standard of engineering, scientific or technical know-how than what existed when the product was placed on the market. However, since a manufacturer is in the business of designing and marketing a particular product, it is held to an

"expert" standard. Plaintiff, therefore, can make out a negligence case by showing proof that the defendant did not stay abreast of the engineering, scientific and technical literature pertaining to its product line. But a defendant can still win by showing it exercised "reasonable care" in design or manufacture even if it did not adopt the "safest possible" practice (see *Cover v. Cohen*, 61 N.Y.2d 261).

'New York courts generally consider strict products liability and negligence claims to be functionally synonymous.' " *Goldin,* 2013 WL 1759575, at *6 (quoting *Pinello v. Andreas Stihl Ag & Co. KG,* No. 08 CV 452(LEK)(RFT), 2011 WL 1302223, at *16 (N.D.N.Y. Mar. 31, 2011)); *see also Colon,* 199 F.Supp.2d at 83 ("for the purposes of analyzing a design defect claim, the theories of strict liability and negligence are virtually identical"). "To make out a prima facie case for negligence in New York, a plaintiff must show (1) that the manufacturer owed plaintiff a duty to exercise reasonable care; (2) a breach of that duty by failure to use reasonable care so that a product is rendered defective, *i.e.* reasonably certain to be dangerous; (3) that the defect was the proximate cause of the plaintiff's injury; and (4) loss or damage." *Colon,* 199 F.Supp.2d at 82. *Simon v. Smith & Nephew, Inc.,* 990 F. Supp. 2d 395, 406 (S.D.N.Y. 2013)

Here however the Plaintiff has failed to highlight any defect in design or flaw in manufacturing, as Plaintiff's expert agrees the batch sheets are all in compliance with quality controls.

On the other hand, it is clear from the evidence to date, that the Plaintiff failed to follow the instructions on the products' label. The Plaintiff admitted that they didn't bother to find out the particular "glue" or bonding agent that is required to be used when the product is to be applied to the head, she did not use the "protective shield adhesive bonder" as described in Step 3.(Id. at 55 and Exhibit I), neither did she understand or bother to find out what step 1: use "before and after

conditioning shampoo, meant from the instructions on the label (Exhibit H at 54 and Exhibit I). Plaintiff is therefore failed to use the product as directed.

CONCLUSION

The Complaint fails to set forth a cause of action on which the Plaintiff is entitled to relief, neither has she established any genuine issue of fact to support any allegation that the Robert's Diamond Bond Product was defective, contained a manufacturing flaw, neither has she shown how the Defendant was negligent in its manufacturing or supply of the product. Plaintiff has also failed to show any breach of warranty or negligence by the Defendant in manufacturing the product. Therefore, the Court should grant the Defendant's Motion to Summary Judgment.

Respectfully submitted

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